Research Proposal Form of the Thesis Entitled

Prevalence of Oral Sub-Mucous Fibrosis among Industrial Workers in Ahmedabad, Gujarat: A Cross Sectional Study

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INTRODUCTION

Every year, approximately six million people die from tobacco usage in the world. The World Health Organization (WHO) estimates that tobacco use contributed to 100 million premature deaths worldwide in the 20th century, and that number is predicted to increase to 1 billion in the 21st century if current trends in tobacco usage continue.[1] According to the National Family Health Survey NHFS 3 survey which was carried out in 2005 it was determined that smoking was more common in men in rural areas and with subjects with an illiterate background.[2] Due to the widespread usage of numerous smoking methods and a wide range of smokeless tobacco (SLT) products, India has a particularly complicated tobacco problem. Many of these goods are produced in cottage and small-scale companies employing a wide range of manufacturing techniques and combinations.[3]

The International Agency for Research on Cancer (IARC) stated that there is enough proof to directly link tobacco use to cancer prevailing in the uterine cervix hypopharynx, oro-pharynx and and naso-pharynx, the nasal cavity the larynx, stomach, pancreas, the kidney and liver.[4]

Tobacco used to be branched into two main themes- the socio cultural structure and belief. Each of the two can be further subdivided into sub-theme, the former being cultural and living conditions, laws, and family and peer relationships and the latter being psychological beliefs, beliefs related to physical influences, and the role of perception of harm.[5]

The term "Vidari" for oral submucous fibrosis (OSMF) initially appeared during the reign of Sushruta. [6] In 1952, Schwartz coined the term "atrophicaidiopathica mucosa oris" to characterize this illness in contemporary literature.[7] Joshi first used the term "oral submucous fibrosis" in 1953.[8]

Jens J. Pindborg and Satyavati M. Sirsat in 1966 defined Oral Submucous Fibrosis as “An insidious chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with a juxta-epithelial inflammatory reaction followed by a fibro-elastic change of the lamina propria, with epithelial atrophy leading to stiffness’’[9].

In 1996, an estimated 2.5 million OSMF cases were reported globally. A marked number of case report investigations have been done in South and South East Asia, etioever data based on population has not been reported.[10] According to findings, OSMF prevails in the range of 0.2

to 2.3% in males and 1.2 to 4.6% in females in India ranging in the age group of 11 to 60 years.[111213] There is a significant increase in the prevalence of this disease since Gutkha, a commercial product of areca nut and tobacco has been widely promoted.[14]

Studies conducted by various renowned authors state that factory workers in various states/ parts of India have a prevalence of OSMF as high as 3.39% in Patna in 2005[15] and 8.9% in 2015 in Delhi.[16]

We included 3998 patients for our study and assessed them for OSMF along with their associated habits to determine the status of the use of SLT in industrial workers of the city.

AIM

To study the prevalence and severity of Oral Submucous Fibrosis (OSMF) among consumers of tobacco infused products, specifically among gutkha, paan, khaini and areca nut chewers working in industrial areas of Ahmedabad, Gujarat.

OBJECTIVES

- To assess prevalence and record staging of OMSF found in the study population consuming gutkha, paan, khaini and areca nut.
- To find out the relationship between various forms of smokeless tobacco and OSMF
- To assess the influence of psycho-social factors on consumption of various forms of smokeless tobacco
- To ascertain the relationship between the subjects who consume various forms of smokeless tobacco and their economic status
- To assess the relationship between educational qualification of the subject and their awareness about their condition
- To determine correlation between the nature of work of the subjects and their awareness about the condition
- To find out the relation between the gender of subjects and awareness about their condition

HYPOTHESIS

1. Generated hypothesis

- Consumption of different types of smokeless tobacco products will lead to development of OSMF in industrial workers.
- There is a significant relationship between SLT consumption and economic status of an individual.
- The amount of tobacco consumed is largely influenced by the psycho-social factors.
- Educational qualification and nature of work of the subject makes them more aware about their condition.

2. Null hypothesis

- Consumption of different types of smokeless tobacco products will not lead to development of OSMF in industrial workers.

REVIEW OF LITERATURE

1. Rajendran, R., Vijayakumar, T., & Vasudevan D. M. (1989)[17]

Oral Sub Mucous Fibrosis is considered to be an alteration of the oral mucosa caused due to a long term vitamin A deficiency, Vitamin B complex deficiency and the lack of Iron intake specifically Folic acid. In this condition, the patient becomes more hypersensitive to irritants like spices, chilies and betel quid. In a host system that already has intrinsic genetic defects, the initiating factors were identified to be the local irritant induced hypersensitivity and the consistent juxta-epithelial inflammatory responses leading to defect in inflammatory-reparative response and ultimately leading to fibrotic healing.

2. Vendhan G., Samira A.,Charles W., (2003)[18]

Based on the study conducted among 4820 non-smoker school children in Tamil Nadu between the age group of 13 to 15 years, one in three students consider that a fellow student who chews or smokes tobacco is more alluring than non-smokers.80% of the students accepted that consumption of tobacco or smoking cigarettes was harmful to their health.

3. Gupta PC, Warnakulasuriya S (2003)[19]

They declared that a significant producer and net exporter of tobacco is South Asia. Smokeless tobacco consumption is more than one-third of the tobacco consumed. Because more people are using processed areca nut products, many of which contain tobacco, oral submucous fibrosis is on the rise. In India, Pregnant females consuming SLT had a threefold increased chance of stillbirth and a two to three times increased risk of delivering a baby that is underweight. Several Indian states have recently outlawed the sale, production, and storage of gutka, a smokeless tobacco product made with areca nut.

4. Dyavanagoudar (2009)[20]

It is noted that OSMF is triggered more quickly by the commercially available freeze-dried tobacco items such as Gutkha, Paan masala and Mawa which release high concentration of areca nut per chew compared to the typically home prepared to betel nut quid which has lower level of areca nut.

5. McClave et al(2010)[21]

Data published by Adult Tobacco Survey (ATS) from 2003-2007 in the United States of America found out that 13.3%-25.4% of adults smoked cigarettes (median: 19.2%); fewer adults smoked cigars (median: 6.4%) or used smokeless tobacco (median: 3.5%). The majority of tobacco users used one tobacco product (median: 82.5%).

6. Gupta B, (2013)[22]

Collected data from The Global Adult Tobacco Survey (GATS), which used a three stage sample methodology to reach a total of 70,802 households, including 42,647 in rural areas and 28,155 in urban areas. Overall tobacco use was reported to be 34.6%, with use among males (47.9%) and in females (20.7%). In comparison to urban areas, which have prevalence rates of 25.3%, the country's rural areas have rates of 38.4%. Overall, smoking bidi (9.0%) is the second

most common method of tobacco consumption after Khaini (12.0%), a smokeless tobacco product.

7. Singh A, Ladusingh L (2014)[23]

They analyzed 69,296 individuals above the age of 15 from Global Adult Tobacco Survey in India. The outcome of the study was considered to be the three forms of current tobacco usage which included smoking tobacco, smokeless tobacco and simultaneous consumption of both. It was established that the rates of tobacco usage was more among uneducated men, belonging to a lower socio-economic status and residing in rural areas.Respondents who were unaware of the health risks of tobacco had greater rates of tobacco use across all forms. Male adults in their middle years were more likely to smoke. All forms of tobacco usage were found to be significantly influenced by age, education, and geographic location. The use of tobacco is substantially impacted by ignorance about some cigarette risks. Policy for control of tobacco in India should follow a specific population-centric method in order to reduce tobacco consumption.

8. Sreeramareddy, et al. (2014)[24]

Based on information gathered from surveys on demographics and health carried out in nine nations (India, Pakistan, Nepal, Bangladesh, Maldives, Philippines, Cambodia, Indonesia, and Timor Leste), it was found that smoking rates among men were particularly high in Bangladesh, Indonesia, and the Maldives. Men and women both used smokeless tobacco, primarily chewable varieties, in a variety of ways, particularly in India. In Bangladesh, the Maldives, Nepal, and Cambodia, chewing tobacco was widespread. Smoking and the use of smokeless tobacco were both linked to older age, less education, and poverty, but their links to residential place and married status varied between men and women among different nations.

9. Niaz K, Maqbool F, Khan F, Bahadar H, Ismail Hassan F, Abdollahi M. (2017)[25]

Conducted a meta-analysis to study the use of tobacco products including paan, gutkha and smokeless tobacco, and the role these chemicals play in the advancement of OSMF and later, Oro-facial cancer. They found out that eating gutkha and continuously chewing paan progressively leads to fibrosis to the submucosal tissue. In conclusion, ingredients used in making paan masala, khaini and gutkha were associated risk factors for OSMF.

10. Karthikeyan H, Ramasubramanian A, Ramanathan V. (2020)[26]

Conducted a survey on 100 participants in Tamil Nadu to determine the awareness of OSMF and its association with tobacco use. 81% of the patients were not aware of the malignancy caused by OSMF.

METHODOLOGY

1. **Source of Data:** This cross-sectional study will be conducted in industrial workers in Ahmedabad district via Universal sampling. The study will be affiliated to the Department of Oral Maxillofacial Surgery, Karnavati School of Dentistry, Karnavati University, Gandhinagar (Gujarat).

2. Method Of Data Collection:

(a) Screening Process:

- Screening of OSMF will be conducted for all the subjects participating in the study.
- The evaluator will be aware about the habit of consumption of smokeless tobacco among the study participants.

(b) Questionnaire:

- A self-prepared questionnaire will be used to gather data from the subjects.
- Answers given by the subjects will be recorded in the questionnaire form.
- It will include questions related to demographic details, literacy and socio-economic status, attitude, consumption of tobacco and its products.
- It will cover in detail about-
  - Habit of consumption of SLT
  - Reason of initiation of habit
  - Psycho-social factors that influence their habit
  - Subjects willing for counselling

(c) Clinical Examination:

- Interincisal mouth opening will be measured using vernier calipers, where-
  - Mouth opening more than 30 mm is considered normal.

- Mouth opening less than 30mm is considered as restricted mouth opening.

- The presence of fibrous bands and blanching will be assesed for every subject.
- Palpation and evaluation of labial/buccal mucosa, faucial pillars, commissures, soft palate and retromolar areas will be performed for the presence of fibrous bands.
- A continuous, dense, non-resilient band like structure palpated intraorally - is considered as a fibrous band.

(d) Assessment of Severity of The Condition

This is based on classification given by Chandramani More in 2011[27].

Clinical staging (CB More et al, 2011):

- Stage 1 (S1): Stomatitis and /or blanching of oral mucosa.
- Stage2 (S2): Presence of palpable fibrous bands in buccal mucosa and/or or pharynx, with /without stomatitis.
- Stage3 (S3): Presence of palpable fibrous bands in buccal mucosa and/or or pharynx, and in any other parts of oral cavity, with/without stomatitis.
- Stage 4 (S4): as follows:

o a. Any one of the above stage along with other potentially malignant disorders, e.g. oral leukoplakia, oral erythroplakia, etc.

o b. Anyone of the above stage along with oral carcinoma.

Functional staging.

- M1:Interincisal mouth opening up to or greater than 35mm.
- M2:Interincisal mouth opening between 25mm and 35mm.
- M3:Interincisal mouth opening between 15mm and 25mm.
- M4: Interincisal mouth opening less than 15mm

3. Inclusion Criteria

- Patients presenting with the history of chewing gutkha/Khaini/paan masala/areca nut/ for 1 or more than 1 year.

- Patients chewing/ consuming tobacco in above mentioned forms with a frequency of 3 or more than 3 packets per day.
- Patients between the age group of 18 to 40 years.

4. Exclusion Criteria

- Patients with reduced mouth opening due to other etiology like temporomandibular joint disorder, odontogenic infections and joint disorders.

RESULT/CONCLUSION EXPECTED

The results expected are as follows:

- A direct relationship exists between SLT and OSMF.
- There is a significant relationship between SLT consumption and economic status of an individual.
- The amount of tobacco consumed is largely influenced by the psycho-social factors.
- Educational qualification and nature of work of the subject makes them more aware about their condition

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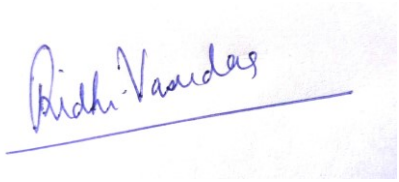

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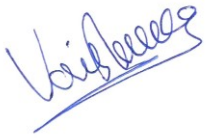

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